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| 10/806,038 | 03/22/2004 | Sally Mackenzie | 1231-218 | 1263 |
| 32905 | 7590 | 08/30/2007 | | |
| JONDLE & ASSOCIATES P.C. 858 HAPPY CANYON ROAD SUITE 230 CASTLE ROCK, CO 80108 | | | EXAMINER KUBELIK, ANNE R | |
| | | | ART UNIT 1638 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/806,038

Applicant(s)

MACKENZIE ET AL.

Examiner

Anne R. Kubelik

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claim 15 is pending.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

3. Claim 15 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The rejection is modified from the rejection set forth in the Office action mailed 1 May 2007. Applicant's arguments filed 14 June 2007 have been fully considered but they are not persuasive.

The claim is broadly drawn to any cytoplasmic male sterile plant made by suppressing the expression of an MSH1-homologous gene in the plant.

The instant specification, however, only provides guidance for identification of the MSH1 gene from Arabidopsis by gene mapping and cloning (example 1), comparison to potential CHM genes from other plant species (examples 2 and 4 and Figs 2-3); and transformation of Arabidopsis with the first 213 of the AtMSH1 gene (example 3). The only other guidance for reducing the expression of MSH1 in a plant is general (§107-112). No cytoplasmic male sterile plant was made by suppressing the expression of an MSH1-homologous gene in a plant.

The instant specification fails to provide guidance for how to make a cytoplasmic male sterile plant made by suppressing the expression of an MSH1-homologous gene in the plant.

The specification in ¶13-14, 34, 107-109 discusses three ways in which MSH-1 expression may be suppressed - 1) by RNAi, antisense, ribozymes or cosuppression (¶107-111), and 2) by a compound, which includes a protein or an antibody (¶13-14, 34, 116-121).

The specification fails to teach RNAi, antisense, ribozyme and cosuppression constructs that can be used to suppress the expression of an MSH1-homologous gene in maize, wheat, rice, sorghum, tomato, potato, soybean and/or millet.

The specification fails to teach how to use a protein or other compound to suppress the expression of an MSH1-homologous gene in a plant.

Sandhu et al (2007, Proc. Natl. Acad. Sci. USA 104:1766-1770) and the Declaration of Sally Mackenzie, filed 21 February 2007, state that mutation of the MSH1 gene in Arabidopsis does not create cytoplasmic male sterile plants (Sandhu et al, pg 1766, right column, paragraph 3; Declaration, pg 1). Thus, the only exemplified transformation would not produce the claimed cytoplasmic male sterile plants.

Further, Sandhu et al teach that suppression of Msh1 in tobacco and tomato required at least one crossing step (Table 1), which is not taught by the instant specification, and not present in the instant claims.

Given the claim breadth, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to develop and evaluate a cytoplasmic male sterile plant made by suppressing the expression of an MSH1-homologous gene in the plant.

Applicant urges that specification lists numerous plants that can be transformed (response pg 3).

This is not found persuasive because plant transformation, per se, if not was is not enabled. What is not enabled is a method of using the DNA, RNA, protein and other compounds to suppress the expression of an MSH1-homologous gene. It is also not clear if a methods of using a protein and other compounds to suppress the expression of an MSH1-homologous gene would even require plant transformation, as such a method is not taught.

Applicant urges that Fig. 3 identifies soybean, tomato, rice, and bean MSH1 consensus sequences (response pg 3).

This is not found persuasive because protein consensus sequences are not the same thing as DNAs or RNAs or other compounds that suppress the expression of an MSH1-homologous gene.

Applicant urges that there is no need for any crossing the investigator introduces and RNAi construction by transformation, regenerated the plants and waits two generations of selfing until male sterility emerges - the additional crossing data in Sandhu is only to confirm that male sterility is truly cytoplasmic (response pg 3).

This is not found persuasive because Applicant admits that two generations of crossing (selfing) are required. These crossing steps are not present in the instant claims.

4. Claim 15 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the

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inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is modified from the rejection set forth in the Office action mailed 1 May 2007.

Applicant's arguments filed 14 June 2007 have been fully considered but they are not persuasive.

The claim is broadly drawn to any cytoplasmic male sterile plant made by suppressing the expression of an MSH1-homologous gene in the plant.

The specification fails to describe the structure of the DNA, RNA, protein or other compound required for the recited function of suppressing the expression of an MSH1-homologous gene in maize, wheat, rice, sorghum, tomato, potato, soybean and/or millet.

No DNA, RNA, protein or other compound species that suppress the expression of an MSH1-homologous gene are described or reduced to practice in the specification.

Because the DNA, RNA, protein and other compounds that suppress the expression of an MSH1-homologous gene are not described, the method of using the DNA, RNA, protein and other compounds to suppress the expression of an MSH1-homologous gene is likewise not described, and the specification fails to provide an adequate written description of the claimed invention.

Further, the specification fails to describe the structural features of plant mutants what are cytoplasmically male sterile because an MSH1-homoglous gene has been suppressed in one of its parents. How does one distinguish a plant that is cytoplasmically male sterile because an MSH1-homoglous gene has been suppressed in one of its parents from a plant that is cytoplasmically male sterile for other reasons?

Therefore, given the lack of written description in the specification with regard to the structural and functional characteristics of the claimed compositions, it is not clear that Applicant

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was in possession of the claimed genus at the time this application was filed at the time this application was filed.

Applicant urges that specification lists numerous plants (response pg 4).

This is not found persuasive because the specification fails to describe the DNA, RNA, protein or other compound required for the recited function of suppressing the expression of an MSH1-homologous gene.

Applicant urges that Fig. 3 identifies soybean, tomato, rice, and bean MSH1 consensus sequences (response pg 4).

This is not found persuasive because protein consensus sequences are not the same thing as DNA, RNA, protein or other compounds that suppress the expression of an MSH1-homologous gene. Additionally, no sequence from millet is provided, and only partial sequences from wheat, potato and sorghum are provided.

Claim Rejections - 35 USC §§ 102 -103

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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7. Claim 15 rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Fauron et al (2002, US Patent 6,346,612).

Fauron et al teach cytoplasmically male sterile maize plants (Fig 1). The prior art plants differ from the claimed plants only by their method of manufacture. However, the claimed method of making the cytoplasmically male sterile plants would not distinguish them over the cytoplasmically male sterile plants taught by the prior art. See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejectable over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products.

Conclusion

8. No claim is allowed

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975.

The central fax number for official correspondence is (571) 273-8300.

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Anne Kubelik, Ph.D.

August 21, 2007



**ANNE KUBELIK, PH.D.
PRIMARY EXAMINER**